

510(k) Summary

Vasomedical, Incorporated
Ambulatory ECG Recorder
Ambulatory ECG Recorder Analysis Software

APR - 1 2009

1. Date Prepared: 20 February 2009
2. Submitter's Name: Vasomedical, Inc.
and Address 180 Linden Ave.
Westbury, NY 11590
3. Contact Person: Melissa M. Purpura
Director, Regulatory and Quality Affairs
Vasomedical, Incorporated
Telephone: (516) 997-4600
Facsimile: (516) 997-2299
E-mail: mpurpura@vasomedical.com
4. **Recorder**
Device Name: Medical Magnetic Tape Recorder
Proprietary Name: Vasomedical Biox 1305, 3 Channel ECG Holter Monitor
Common Name: 1305 Biox Holter
Classification Name: 870.2800 Medical Magnetic Tape Recorder

Analysis Software
Device Name: Computer, Diagnostic, Programmable
Proprietary Name: Vasomedical Biox ECG Analysis System Software
Common Name: CB Series Software
Classification Name: 870.1425 Computer, Diagnostic, Programmable
5. Predicate Device: The AECG Recorder listed above is substantially equivalent to the Huntleigh Healthcare Cardiology Products Division Recorder Models MedilogAR4 and MedilogAR12. The AECG Analysis Software listed above is substantially equivalent to the Huntleigh Healthcare Cardiology Products Division, Medilog Darwin. FDA granted 510(k) clearances for this predicate device on April 6, 2007 under K070818 and December 22, 2005 under K053369.
6. Device Description: Vasomedical's Ambulatory ECG Recorder Model 1305 is intended to be used as a Holter ambulatory electrocardiograph monitor for the purpose of screening ECG rhythms for periods up

to 72 hours. Cardiac rhythm is acquired by 3 channel ECG signals. The recorders are intended for adults and children over the age of six years old.

The recorders are portable, microprocessor based devices that are worn by a patient with the use of a carrying case and strap.

1305 Biox Holter specifications are noted in table 1.

Lead	3
Electrode	5 or 7
Lead wire type	Lead-7C/5C
Display	LED
Batteries	1 "AA" alkaline
Dimensions	3.3" x 2.3" x 0.8"
Storage Medium	SD Card
Memory	1 GB or more
Sample Rate	256 Hz/channel; 10,000 Hz/channel for pacemaker; 1,000 Hz/channel with SAECG option
Resolution	10 bit, 12 bit for SAECG option

Table 1: Specification of 1305 Biox Holter.

Vasomedical's Ambulatory ECG CB Series Analysis System Software allows transfer of data from the recorder to a Windows based PC via a removable storage card for the purpose of creating printouts and reports. These data are used by physicians for diagnostic evaluations.

Vasomedical's Ambulatory ECG Analysis System Software features are noted in table 2.

QRS classification	Ventricular, Supra-Ventricular, Normal, Artifact
Comprehensive event reports	VE, VE pair, VE bigeminy, V-run, R on T, SVE, SVE pair, SVE-run, pause, long RR, tachycardia, bradycardia, and atrial fibrillation
ST-segment reports	Deviation, Slope, Duration, Heart rate
Analysis capability	Arrhythmia, ST-segment, HRV, pacemaker, atrial fibrillation, SAECG, HRT
Viewing modes	Standard ECG, ECG thumbnail, Page scanning
Data reporting	Trend charts, statistical tables, category specific histograms

Table 2: Features of CB Series Software.

7. Intended Use: The Ambulatory ECG Recorder described in this 510(k) Premarket Notification is a non-invasive device intended to acquire, record and store ambulatory three (3) channel ECG signals from the upper body surface of adult and adolescent patients for a minimum of 24 hours. It works in concert with the CB Series Analysis Software to playback, review, analyze, edit and print ECG data.
8. Comparison of Technological Characteristics: Technological and functional characteristics of the devices listed in this 510(k) Premarket Notification are essentially the same as those of the predicate devices. The devices listed in this 510(k) Premarket Notification are therefore substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

Vasomedical, Inc.
c/o Ms. Melissa M. Purpura
Director, Regulatory and Quality Affairs
180 Linden Avenue
Westbury, NY 11590

Re: K083820

Trade/Device Name: Vasomedical Biox 1305, 3 Channel ECG Holter Monitor and
Ambulatory ECG Analysis System Software CB Series

Regulation Number: 21 CFR 870.2800

Regulation Name: Medical Magnetic Tape Recorder

Regulatory Class: Class II (two)

Product Code: DSH

Dated: February 20, 2009

Received: February 24, 2009

Dear Ms. Purpura:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

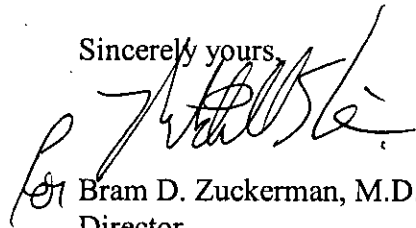
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: Vasomedical Biox 1305, 3 Channel ECG Holter Monitor
Ambulatory ECG Analysis System Software CB Series

Indications for Use:

The Ambulatory ECG Recorder described in this 510(k) Premarket Notification is a non-invasive device intended to acquire, record and store ambulatory three (3) channel ECG signals from the upper body surface of adults and children over the age of six years old for a minimum of 24 hours. It works in concert with the CB Series Analysis Software to playback, review, analyze, edit and print ECG data. The software does not perform diagnostics. These data are used by physicians for diagnostic evaluations.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRL, Office of Device Evaluation (ODE)


(Division Sign-Off) 3/31/09
Division of Cardiovascular Devices510(k) Number K083820Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____